APPENDIX I

DEVELOPMENT OF LEAD CLEANUP LEVELS

Technical Memorandum

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To: FTMC IRON MOUNTAIN ROAD RANGES EE/CA FILE

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Subject: **DEVELOPMENT OF LEAD CLEANUP LEVELS FOR THE "OPEN SPACE" SCENARIO FOR THE IRON MOUNTAIN ROAD FIRING RANGES: REVISION 1.**

1.0 Introduction

The purpose of this task is to develop cleanup levels for lead at some former shooting ranges on Fort McClellan (FTMC). Lead was released as a result of handling and discharge of lead-based ammunition in firearms. It is the intent of FTMC and the Mobile Office of the U.S. Army Corps of Engineers (USACE) to comply with the site-use scenarios proposed in the *Comprehensive Reuse Plan* (FTMC, 1997), which identifies "residential use" and "open space" as the two future reuse options for the sites in question.

Potentially contaminated media of interest at the shooting ranges include soil, sediment and surface water. However, surface water bodies on the Iron Mountain Road ranges are ephemeral in nature, so that exposure is likely to be infrequent and too uncertain to be predictable or quantifiable. Therefore, exposure to surface water is not included, and sediment is evaluated as soil for the purpose of estimating exposure. This memorandum develops cleanup levels for lead in soil for the most highly exposed receptor under the "open space" reuse scenario.

A cleanup level for lead of 400 mg/kg in soil for residential exposure was developed in the subject EE/CA and defended in the response to the January 2001 Independent Technical Review (ITR) report (ITR, 2001). The 400 mg/kg value was developed by applying site-specific data, to the extent that they were available, to the EPA (1994a) Integrated Exposure Uptake Biokinetic (IEUBK) model for predicting blood lead levels in young children.

2.0 Toxicity Assessment

Lead is classified as a cancer weight-of-evidence Group B2 chemical "probable human carcinogen" on the basis of sufficient evidence in animals and inadequate evidence in humans (EPA, 2001). The human data consist of four occupational exposure studies of lead smelter and/or lead battery workers. All of the occupational studies lack quantitative exposure information, as well as information on the possible contribution from smoking. All studies also include exposures to other metals such as arsenic and cadmium, both of which are associated with carcinogenicity, for which no adjustment was done. The animal data include ten rat bioassays and one mouse assay that have shown statistically significant increases in renal tumors with dietary and subcutaneous exposure to several soluble lead salts. Animal assays provide reproducible results in several laboratories, in multiple rat strains, and with some evidence of multiple tumor sites. Short term studies show that lead affects gene expression, which contributes to the weight of evidence for a carcinogenic role. The data are inadequate for development of a cancer slope factor from which a cleanup level for lead could be estimated.

The regulation of lead in environmental media is generally based on its potential to induce noncancer effects. A plethora of information on the health effects of lead has been obtained through decades of medical observation and scientific research (EPA, 2001). By comparison to most other environmental contaminants, the degree of uncertainty about the health effects of lead is quite low. It appears that some of these effects, particularly changes in the levels of certain blood enzymes and in aspects of children's neurological and neurobehavioral development, may occur at blood lead levels so low as to be essentially without a threshold. The EPA RfD Work Group discussed inorganic lead (and lead compounds) at two meetings and considered the development of an RfD for inorganic lead to be inappropriate.

In the absence of an RfD for lead, other methods have arisen to estimate safe levels in environmental media. The 400 mg/kg residential soil cleanup level, for example, is based on estimations of blood lead levels in very young children, the most highly exposed and physiologically the most sensitive receptor in a residential setting (EPA, 1994b). Blood lead levels in children are estimated with the EPA (1994a) IEUBK model that calculates the geometric mean blood lead concentration, generates a probability density plot, and estimates the percent of a hypothetical population that may have blood lead levels exceeding a cutoff level, generally accepted to be 10 micrograms per deciliter (μg/dL). A pregnant women represents the most sensitive adult receptor because of potential neurological damage to the fetus.

The EPA Technical Review Workgroup for lead examined several adult blood lead models, but currently recommends only one for developing cleanup levels in environmental media (EPA, 1996). They acknowledge, however, that other models provide useful information, particularly regarding the time-course of blood lead concentrations during brief or acute exposures, and that the recommended model is intended for adults who have relatively steady exposure patterns; i.e., at least one day per week over at least a 90-day period (13 days in a 90-day period). The model tends to overestimate blood lead levels for less frequent exposure scenarios because it is not designed to account for the time required to attain steady state (Maddaloni, 2000).

3.0 Exposure Assessment

The recreational site user was selected as the most intensely exposed receptor for land designated as open space (IT, 1998). The recreational site user scenario developed for the purpose of estimating SSSLs is a 7- to 16-year-old youth who visits the site on 2 days per week for 4 hours per day for purposes of hiking, playing, nature walks, hunting, or other recreational activities. The youth, rather than an adult or child, was selected for SSSL development to be consistent with EPA (1995) Region IV guidance for a trespasser scenario, and to capture the greater conservatism of the lesser average body weight of the youth compared with an adult. However, a pregnant woman is probably the receptor most sensitive to lead that might regularly visit a site for recreational purposes, and is chosen for development of cleanup levels for lead in media for open space.

The receptor scenarios developed for SSSL estimation are based on the EPA (1989, 1991) reasonable maximum exposure (RME) paradigm to ensure adequate protectiveness. An RME evaluation usually selects upper bound estimates for ingestion rate and exposure frequency, and central tendency (CT) estimates for some other variable values such as body weight. The relevant exposure assumptions for the recreational site user from IT (1998) are summarized in Table 1.

It is inappropriate, however, to use RME values in either the IEUBK model or the adult blood lead model because both models have a statistical module that addresses the variability about exposure (e.g., ingestion rate) and physiological parameters (e.g., bioavailability) to estimate blood lead level. Therefore, CT estimates of the exposure variables should be used, and are derived and presented in Table 1. Justification for the CT variable values is presented in the footnotes in Table 1. However, further clarification may be helpful. For example, it is assumed that the soil incidental ingestion rate for a recreational site user is similar to that for a resident, but the rate is factored downward to reflect the fraction of a waking day spent on site (IT, 1998).

The exposure pathways and variables discussed above are relevant to ingestion. Dermal contact with soil, sediment and surface water was also evaluated for SSSL development because many chemicals, such as some semivolatile organic compounds, are readily absorbed by the skin. Dermal uptake of lead, however, is not expected to be significant (EPA, 1990, 1994a) and is not considered further.

The CT exposure variables in Table 1 can be applied to the EPA (1996) adult blood lead model to estimate a cleanup level for lead in soil for the recreational site user. The cleanup level is understood to be the lead concentration averaged over an exposure unit, defined as the entire area over which the receptor is expected to be randomly and uniformly exposed. There is no basis to predict what physical site features would be most attractive for a recreational site user, given the myriad of recreational purposes for which a visit might occur. Therefore, it is assumed that the largest contiguous open space area, whether within a single range or across multiple ranges, constitutes an exposure unit for soil.

4.0 Estimating Cleanup Levels for Lead in Soil for the Recreational Site User

The EPA (1996) model was first used to develop cleanup levels for lead in soil in an occupational exposure scenario. The model consists of the following algorithm and default assumptions:

$$PbB_{adult,central} = PbB_{adult,0} + \frac{PbS \cdot BKSF \cdot IR_S \cdot AF_S \cdot EF_S}{AT} \tag{1}$$

where the variable definitions and their default values are:

$PbB_{adult,\ central}$	=	CT estimate of blood lead concentration (μg/dL) in women of child-bearing age, calculated.
$PbB_{adult,0}$	=	typical background blood lead concentration (1.7 to 2.2 μg/dL) in women of child-bearing age

PbS	=	soil lead concentration (microgram/gram [μg/g], which is equivalent to milligram per kilogram [mg/kg])
BKSF	=	biokinetic slope factor relating increase in typical adult blood lead concentration to average daily lead uptake (0.4 μg/dL blood lead increase per microgram per day [μg/day] lead uptake)
IR_S	=	soil intake rate (0.05 grams per day [g/day])
AF_S	=	gastrointestinal absorption factor for lead in soil (0.12 unitless fraction)
EF_S	=	exposure frequency (219 total days of exposure [employment] during the averaging period [one year])
AT	=	averaging time (1 year [365days]).

EPA (1996) rearranged and modified Equation 1 to derive an equation by which a risk-based remedial goal (RBRG), analogous to a cleanup level, for lead in soil can be estimated:

$$RBRG = \frac{(PbB_{adult,central,goal} - PbB_{adult,0}) \cdot AT}{BKSF \cdot IR_S \cdot AF_S \cdot EF_S} \qquad (2)$$

where the variable definitions and their default values are:

RBRG	=	risk-based remedial goal (analogous to cleanup level) for lead in soil (μg/g, equivalent to mg/kg), calculated
$PbB_{adult,central,goal}$	=	goal for CT estimate of blood lead concentration (μg/dL) in women to ensure that fetal blood levels (in 95 percent of population) do not exceed 10 μg/dL
$PbB_{adult,0}$	=	typical background blood lead concentration (1.7 to 2.2 μg/dL) in women of child-bearing age (average of 2.0 μg/dL used in this evaluation)
AT	=	averaging time (365 days).
BKSF	=	biokinetic slope factor relating increase in typical adult blood lead concentration to average daily lead uptake (0.4 μg/dL blood lead increase per μg/day lead uptake)
IR_S	=	soil intake rate (0.05 grams per day [g/day])
AF_S	=	gastrointestinal absorption factor for lead in soil (0.12 unitless fraction)
EF_S	=	exposure frequency (219 total days of exposure [employment] during the averaging period [one year]).

$PbB_{adult,central,goal}$, is estimated as (EPA, 1996):

$$PbB_{adult,central,goal} = \frac{PbB_{fetal,0.95,goal}}{GSD_{i,adult}^{1.645} \cdot R_{fetal/maternal}} \qquad (3)$$

where the variable definitions and their default values are:

$PbB_{adult,central,goal}$	=	goal for CT estimate of blood lead concentration (µg/dL) in women to ensure that fetal blood levels (in 95 percent of population) do not exceed 10 µg/dL, calculated
$PbB_{fetal,0.95,goal}$	=	goal for the 95th percentile blood lead concentration (generally accepted to be 10 µg/dL)
$GSD_{i,adult}$	=	individual geometric standard deviation among adults that have similar site-related exposures, but dissimilar responses to site-related exposures and dissimilar background exposures (value of 2.1 selected for a heterogeneous population)
$R_{fetal/maternal}$	=	proportionality constant between fetal blood lead level and maternal blood lead level at birth (0.9).

From Equation 3 and the variable values provided by EPA (1996) $PbB_{adult,central,goal}$ is estimated as follows:

$$PbB_{adult,central,goal} = \frac{10}{2.1^{1.645} \cdot 0.9} = 3.3\,\mu g / dL \tag{4}$$

The $PbB_{adult,central,goal}$ - $PbB_{adult,0}$ term in Equation 2 can be replaced with:

$$3.3 - 2.0 = 1.3\,\mu g / dL \tag{5}$$

Preliminary cleanup goals for lead in soil can be estimated for the recreational site user by substituting actual default and site-specific values in Equation 2:

$$RBRG = \frac{1.3 \cdot 365}{0.4 \cdot 0.0125 \cdot 0.12 \cdot 104} = 7604\ mg / kg \tag{6}$$

Site-specific variable values in Equation 6 include the IR_S of 0.0125 g/day, and the CT EF_S of 104 days/year and the FI of 0.25 from Table 1. The IR_S is the product of the CT soil incidental ingestion rate of 0.05 g/day and the FI of 0.25. The preliminary cleanup level for lead in soil for the recreational site user is 7604 mg/kg, which, rounded to two significant figures to reflect the uncertainty associated with the model, is 7600 mg/kg.

5.0 Uncertainties

The EPA (1994a) IEUBK model and the EPA (1996) adult blood lead model are among the most rigorously validated of the models generally used in risk assessment. Their use introduces little uncertainty into the evaluation.

The EPA (1996) adult blood lead model addresses incidental ingestion but does not include the potential contribution from dermal exposure. Dermal uptake, however, is not considered a significant route of absorption for inorganic lead (EPA, 1990, 1994a). The fact that dermal exposure is not included in the adult blood lead model is judged not to be a significant source of uncertainty in estimation of the RBRG.

Probably the greatest uncertainty arises from the hypothetical exposure assumptions applied to the recreational site user. This receptor scenario, however, was selected to represent the most intense exposure plausible, and the exposure variable values were chosen to bias the evaluation toward increased conservatism (IT, 1998). Although the uncertainty is great, it is unlikely that risks would be underestimated or cleanup levels would be overestimated.

6.0 References

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U.S. Environmental Protection Agency (EPA), 2001, ***Integrated Risk Information System (IRIS)***, National Center for Environmental Assessment, Cincinnati, OH, on line.

Table 1

Pathway Variable[a]	Units	Recreational Site User	
		RME[a]	CT
Soil Exposure Pathways			
Soil incidental ingestion rate (IR)	g/day	0.1	0.05[b]
Fraction of exposure to site soil (FI)	unitless	0.25	0.25[c]
Exposure frequency (EF)	days/year	104[d]	104[c]

RME = reasonable maximum exposure; CT = central tendency
[a]Please see IT Corporation (IT), 1998, Final ***Installation-Wide Work Plan, Fort McClellan, Alabama***, Prepared for the U.S. Department of the Army, Mobile District, Corps of Engineers, August, unless otherwise specified, for development and defense of relevant exposure pathways and RME variable values.
[b]U.S. Environmental Protection Agency (EPA), 1997, ***Exposure Factors Handbook***, Office of Research and Development, National Center for Environmental Assessment, Washington, DC, August, EPA/600/P-95/002Fa.
[c]RME values are used where CT values cannot be estimated.
[d]Based on the assumption that exposure would occur on 2 days per week, 52 weeks per year.